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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,695	12/13/2004	Mark J Evans	36119.159US4	1897

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WilmerHale/Wyeth
60 STATE STREET
BOSTON, MA 02109

EXAMINER	
ZARA, JANE J	

ART UNIT	PAPER NUMBER
1635	

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09/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,695	EVANS ET AL.	
	Examiner	Art Unit	
	Jane Zara	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-67* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-14, 16, 20, drawn to a method for identifying an effective agent comprising detecting a detectable substance in cell culture.

Group II, claim(s) 17, drawn to a method for identifying an effective agent comprising administering an agent to a first and second cell culture.

Group III, claim(s) 15 and 18, drawn to a method for identifying an effective agent comprising cloning NF-κ –β promoter.

Group IV, claim(s) 19, drawn to a method for identifying an effective agent comprising administering an agent to a first and second cell culture, which second culture expresses SHP and HNF4-α and further comprises either CYP7A or CYP8B1.

Group V, claim(s) 21 and 67, drawn to a method of preventing or ameliorating a condition in a subject.

Group VI, claim(s) 22-42, 63-66, drawn to a composition comprising an effective inhibitory agent.

Group VII, claim(s) 43-58, drawn to a composition comprising a promoter/detectable substance gene reporter.

Group VIII, claim(s) 59-62, drawn to a composition comprising a non-naturally deactivated SHP or farnesoid X receptor complex.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Claims 1, 2, 4, 9, 12, 14, 16, 17, 18, 19, 20, 21, 24, 26, 27, 32, 35-42, 46-49, 51, 54, 59, 63-65, all of which are encompassed by claims 1-67, are drawn to a plurality of target genes, antisense sequences, inhibitory agents, cell culture types, reporter genes, plasmids and vectors, promoters, genes to be incorporated into promoter/reporter constructs, treatable conditions, as well as immature and mature forms of target proteins, all of which are set forth in improper Markush groupings. Therefore, this application does not comply with the requirements for unity of invention (Rules 13.1, 13.2 and 13.3) for the following reasons:

According to the guidelines in section (f)(i)(a) of annex B of the PCT Administrative Instruction, the special technical feature as defined by PCT Rule 13.2 shall be considered to be met when all the alternatives of a Markush group are of similar nature. For chemical alternatives, such as the claimed oligonucleotide sequences, target proteins, chemical and biological agents, promoter/reporter constructs, nucleic acid constructs and reporter molecules, the Markush groups shall be rearded as being of similar nature when (A) all alternatives hav e common property or activity AND (B)(1) a common structure is present, i.e., a significant structure is shared by all the alternatives OR (B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to an art recognized class of compounds in the art to which the invention pertains.

The instant agents, nucleic acid constructs, target genes, vectors, etc set forth in and/or encompassed by claims 1-67 are considered to be each separate inventions for the following reasons:

The different sequences and structures do not meet the criteria of (A), common property or activity or (B)(2), art recognized class of compounds. In the instant case, the different sequences are structurally and chemically and biologically different and distinct, and the different antisense target a different and specific region of a target gene and modulate the expression of that gene to varying degrees. Each member of the class cannot be substituted one for the other with the expectation that the same intended result would be achieved.

Further, the different Groups of compounds and nucleic acid and protein constructs do not meet the criteria of (B)(1) as they do not share, one with another, a common core structure. Accordingly, unity of invention between the instant oligonucleotide sequences is lacking and each oligonucleotide sequence claimed is considered to constitute a special technical feature.

Applicant is therefore advised to elect a single target gene, antisense sequence or inhibitory agent, cell culture type, reporter gene, plasmid or viral vector, promoter for the elected construct, gene to be incorporated into the elected promoter/reporter construct, treatable condition, as well as electing one immature or mature form of target protein.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Conclusion

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94

(December 28, 1993) (see 37 C.F.R. ' 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane Zara whose telephone number is (571) 272-0765. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz, can be reached on (571) 272-0763. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jane Zara
9-18-07